UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,019	04/17/2007	Helle Wittorff	05198-P0017A	4929

24126 7590 12/15/2011

ST. ONGE STEWARD JOHNSTON & REENS, LLC
986 BEDFORD STREET
STAMFORD, CT 06905-5619

EXAMINER	
GWARTNEY, ELIZABETH A	
ART UNIT	PAPER NUMBER
1781	
MAIL DATE	DELIVERY MODE
12/15/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,019	WITTORFF, HELLE	
	Examiner	Art Unit	
	ELIZABETH GWARTNEY	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-4 and 8-32* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-4 and 8-32* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 September 2010 has been entered.

2. The previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn in light of Applicants' amendment and submission filed 16 September 2010.

3. Claims 5 and 6 have been cancelled. **Claims 1-4 and 8-32 are pending.**

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 15, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Regarding **claim 15**, the recitation "wherein natural resins provide an improved and sticky texture of the gum base when applied in chewing gum formulation" renders the claim indefinite. The recitation merely recites what properties natural resins bring to the gum base composition when used in a chewing gum formulation does not state that the gum base granules of claimed comprise natural resins.

Claim 27 recites the limitation "said chewing gum polymers" in line 2. There is insufficient antecedent basis for this limitation in the claim. While **claim 1** requires at least one biodegradable gum base polymer, there is no reference to chewing gum polymers generally.

Regarding **claim 28**, the recitation "wherein said gum base granules are blended and compressed together with chewing gum ingredients, wherein the chewing gum ingredients are sweetener, flavor, fillers and emulsifiers" renders the claim indefinite. Based on the present specification (see Example 2/gum based granule composition) which provides for chewing gum base compositions comprising sweetener, flavor, fillers and emulsifiers, it is unclear if the claimed ingredients are in addition to or part of the chewing gum base composition. The present specification discloses a chewing gum comprising chewing gum base, filler, sweetener and flavor but not emulsifier. With respect to the prior art the gum base composition encompasses chewing gum ingredients.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1, 2, 4, 9-10, 13, 19, 23, 24, 26 and 18-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leadbeater et al. (US 2005/0220934) in view of Grijpma et al. (US 5,672,367).**

Regarding **claims 1, 2, 4 and 24**, Leadbeater et al. disclose gum base granules for tabletted chewing gum (i.e. compressed gum) comprising elastomeric polymers (Abstract, [0009]). Leadbeater et al. disclose that the gum base may be any gum base well known to those skilled in the art ([0009]). Leadbeater does not disclose gum base granules comprising at least one biodegradable gum base polymer wherein the gum base has a water content of less than 1.0% by weight of the gum base.

Grijpma et al. teach a chewing gum base including one or more biodegradable polymers and free of non-biodegradable polymers (C1/L45-55, Claim 1). Specifically, Grijpma et al. teach replacing conventional, non-degradable elastomers that are used in the gum base of chewing gum by biodegradable polymers selected from the group of polyesters and polycarbonates (Abstract, C1/L21-25) Grijpma et al. teach polyesters based on the polymerization product of one or more cyclic esters (C1/L49-55, C3/Example 1). Grijpma et al. teach that the polymers contain chemically unstable bonds in the polymer chain which are preferably broken down under the influence of light or hydrolytically into components that are water-soluble and non-toxic (C1/L39-42).

Leadbeater et al. and Grijpma et al. are combinable because they are concerned with the same field of endeavor, namely, chewing gum base compositions comprising elastomeric

polymers. Given Leadbeater et al. disclose gum base granules wherein the gum base may be any gum base well known to those skilled in the art, since Grijpma et al. disclose replacing conventional, non-degradable elastomers that are used in the gum base of chewing gum by biodegradable polymers, it would have been obvious to one of ordinary skill in the art at the time of the invention to have replaced the non-degradable elastomers in the gum base of Leadbeater with biodegradable polymers, as taught by Grijpma et al. Moreover, by doing so, in combination with other biodegradable additives, a chewing gum would be obtained whose organic components are biodegradable after use.

Given Grijpma et al. teach that the biodegradable polymers of their invention are known to be hydrolytically unstable (*see* wherein chemically unstable bonds in the polymer chain are broken down hydrolytically - C1/L39-41), one ordinary skill in the art wishing to employ the biodegradable polymers of the prior art would have been motivated to formulate a chewing gum base comprising the minimal amount of water to maintain the stability of the polymers. Finding the optimum amount of water to be included in the checking gum base would require nothing more than routine experimentation by one of ordinary skill in the art.

With regards to **claims 9-10**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. While Grijpma is silent with respect to polymer molecular weight, since claim 9 includes an amount of about 0%, the limitations of claims 9 and 10 have been satisfied.

With regards to **claim 13**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Given Leadbeater et al. does not disclose gum base granules including sweetener (*see* [0009] wherein gum base is plasticized rubber or polymer with added texturizer,

anti-tacking agents and antioxidants), since 0% falls with a range of less than 50% by weight, the limitations of claim 13 have been satisfied.

Regarding **claim 19**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Leadbeater et al. also disclose gum base granules comprising active ingredients ([0017]-[0025]).

Regarding **claim 23**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Leadbeater et al. disclose wherein the chewing gum base granules comprise flavoring ([0011]).

Note, with regards to the method limitations recited in claim 23, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself.

Regarding **claim 26**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Leadbeater et al. disclose a tabletted chewing gum produced from granulated gum base (Abstract, [0027]).

Regarding **claim 28**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Leadbeater et al. disclose tabletted chewing gum comprising granulated gum base, sorbitol (i.e. filler and sweetener), spearmint flavor and color ([0009], [0035]); wherein the granulated gum base comprises and emulsifier (*see* wherein gum base ARTICA -T is composed of glycerol esters of edible fatty acids ([0009]).

Regarding **claims 29 and 30**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Leadbeater et al. is silent with respect to water content.

Given Grijpma et al. teach that the biodegradable polymers of their invention are known to be hydrolytically unstable (*see* wherein chemically unstable bonds in the polymer chain are broken down hydrolytically - C1/L39-41), one ordinary skill in the art wishing to employ the biodegradable polymers of the prior art would have been motivated to formulate a chewing gum comprising the minimal amount of water to maintain the stability of the polymers. Finding the optimum amount of water to be included in the chewing gum base would require nothing more than routine experimentation by one of ordinary skill in the art.

Regarding **claim 31**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Given Grijpma et al. teach gum base comprising ***at least one biodegradable polymer***, the limitations of claim 31 are satisfied.

Regarding **claim 32**, modified Leadbeater et al. disclose all of the claim limitations as set forth above. Given Leadbeater et al. disclose non-biodegradable gum base granules, since Grijpma et al. teach replacing conventional, non-degradable elastomers that are used in the gum base of chewing gum by biodegradable polymers selected from the group of polyesters and polycarbonates, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined both types of chewing gum granules, i.e. those with and without degradable elastomers, to make a chewing gum with a desired level of degradability.

9. **Claims 1-3, 8-18, 20-23 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gmunder et al. (US 6,200,608) in view of Leadbeater et al. (US 2005/0220934) and Bunczek et al. (US 6,017,566).**

Regarding **claims 1, 3, 8 and 25**, Gmunder et al. disclose particulated gum base comprising elastomer, elastomer plasticizer and filler (C2/L12-18). Gmunder et al. teach that the gum base ingredients are particles 0.6 mm or less (C6/L13-18) and the gum base is free of liquid ingredients (C2/L36-37).

Gmunder et al. is silent with respect to the use of particulated gum base for a compressed chewing gum. Further, Gmunder et al. does not disclose biodegradable elastomers or water content.

Leadbeater et al. teach that it was known to use gum base granules to make tabletted or compressed chewing gum (Abstract, [0009], [0027]). Given Gmunder et al. disclose particulated gum base, since Leadbeater et al. teach that it was known to make compressed chewing gum with particulated gum base wherein the gum base is any gum base well known to those skilled in the art, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the particulated gum base of Gmunder et al. to make compressed chewing gum.

Bunczek et al. teach a gum base comprising approximately 1 to about 80% by weight biodegradable polymer, i.e. polyester, produced through reaction of at least one alcohol and at least one acid including carboxylic acids (C1/L53-62, C2/L45-46, C3/L23, C4/L42-43, C9/L62-C10/L3) and about 20 to about 60% by weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L4-21). Bunczek et al. teach that the gum base is biodegradable (C2/L59-61).

Bunczek et al. and Gmunder et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the elastomer system taught by

Bunczek et al. comprising 1 to 80% by weight biodegradable polymer and 20 to 60% synthetic elastomer, for that used in Gmunder et al., for the purpose of making a biodegradable gum base.

With respect to water content, given biodegradable polymers are known to be hydrolytically unstable, one ordinary skill in the art wishing to employ the biodegradable polymers of the prior art would have been motivated to formulate a chewing gum comprising the minimal amount of water to maintain the stability of the polymers. Finding the optimum amount of water to be included in the chewing gum base would require nothing more than routine experimentation by one of ordinary skill in the art.

Regarding **claim 2**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Bunczek et al. teach gum base composition with an elastomer system comprising biodegradable polymer, i.e. polyester, and free of non-biodegradable polymers (*see* for example C8/Base Examples 1-3).

Regarding **claims 9-10**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Given that Bunczek et al. does not teach at least one high molecular weight elastomeric biodegradable polymer, it is clear that the amount of high molecular weight elastomeric biodegradable polymer in the gum base would be 0%. Further, given Bunczek et al. teach 0% of a high molecular weight elastomeric biodegradable polymer, it is clear that the limitations of claim 10 are met.

Regarding **claims 11-12**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Bunczek et al. also teach that the gum base comprises about 20 to about 60 wt % of a synthetic elastomer including polyvinyl acetate having a weight average molecular weight of about 2,000 to 90,000 g (C10/L45-60).

Regarding **claim 13**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Given Gmunder et al. does not disclose that the gum base comprises sweetener (*see* for example, C8/Table 1), it is clear that the gum base comprises sweetener in an amount of less than 50% by weight.

Regarding **claim 14**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Given Gmunder et al. do not disclose a gum base comprising lubricants, anti-adherents and glidants the limitation of claim 14 is met (*see* C8/Table 1, C10-12/Table 3).

Regarding **claim 15**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. also disclose that the gum base comprises natural rosin ester, i.e. natural resins (C11/L16-17). Given Gmunder et al. disclose a gum base comprising natural resins, it is clear that the natural resins would intrinsically provide an improved and sticky texture of the gum base when applied in chewing gum formulations.

Regarding **claims 16-18**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. also disclose that the gum base if free of wax (C6/L50-52), or fat (*see* wherein the preferred softeners comprised de-oiled lecithin, glycerol monostearate and mono and di-glycerides- C7/L20-23) and comprises about 0 to 70 wt% filler (C7/L40-52, C8/Table 1).

Regarding **claim 20**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. also discloses that the gum base comprises about 0% to about 80% by weight elastomer plasticizer, i.e. synthetic resin, including terpene resins (C4/L51-C5/L10, C8/Table 1)

Regarding **claim 21**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. also disclose that the gum base comprises from about 4 to about 34% by weight softener (including lecithin, glycerol monostearate and mono and di-glycerides – C7/L20-223).

Regarding **claim 22**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. disclose that the gum base may comprise from 1 to 6% wax (C4/L34-50, C10-12/Table 3).

Regarding **claim 23**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. also discloses mixing flavoring agents into the gum base prior to forming into a chewing gum (C2/L24-32).

Regarding **claim 26**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Given Gmunder et al. disclose particulated gum base, since Leadbeater et al. teach that it was known to make compressed chewing gum with particulated gum base wherein the gum base is any gum base well known to those skilled in the art, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used the particulated gum base of Gmunder et al. to make compressed chewing gum.

Regarding **claim 27**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Bunczek et al. also teach a gum base elastomer system comprising about 20 to about 60% by weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L45-48).

Regarding **claim 28**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. disclose that in general a chewing gum composition comprises a water-soluble bulk portion, water insoluble chewable gum base portion and water insoluble

flavoring agents (C3/L9-15). While Gmunder et al. disclose chewing gums made from the chewing gum base granules (C11/L59-60), the reference is silent with respect to the chewing gum ingredient or water-soluble bulk portion. However, Bunczek et al. teaches that it was known to mix gum base with chewing gum ingredients including sweeteners, flavorings, fillers, and emulsifiers to making chewing gum (C11/L46-52, C12/L55-61).

Regarding **claims 29-30**, modified Gmunder et al. disclose all of the claim limitations as set forth above. With respect to water content, given biodegradable polymers are known to be hydrolytically unstable, one ordinary skill in the art wishing to employ the biodegradable polymers of the prior art would have been motivated to formulate a chewing gum comprising the minimal amount of water to maintain the stability of the polymers. Finding the optimum amount of water to be included in the chewing gum would require nothing more than routine experimentation by one of ordinary skill in the art.

Regarding **claim 31**, modified Gmunder et al. disclose all of the claim limitations as set forth above. Bunczek et al. also teach an elastomer system comprising two biodegradable polymers (C9/Base Examples 8).

Regarding **claim 32**, modified Gmunder et al. disclose all of the claim limitations as set forth above. While modified Gmunder et al. disclose biodegradable gum base granules in a formed chewing gum, the references do not disclose wherein said biodegradable gum base granules are used together with conventional non-biodegradable gum base granules.

Given Gmunder et al. teach non-biodegradable gum base granules, since modified Gmunder et al. disclose biodegradable gum base granules, it would have been obvious to one of

ordinary skill in the art at the time of the invention to have combined both types of granules to make a chewing gum with a desired level of degradability.

10. **Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gmunder et al. (US 6,200,608) in view of Leadbeater et al. (US 2005/0220934) and Bunczek et al. (US 6,017,566) as applied to claim 1, and further in view of Wittorff et al. (WO 02/076230).**

Regarding claim 19, modified Gmunder et al. disclose all of the claim limitations as set forth above. Gmunder et al. does not disclose a chewing gum base granule composition comprising active ingredients.

Wittorff et al. teach that it was known to admix chewing gum base with chewing gum additives including pharmaceutically or biologically active substances (p. 16/L8-15, p. 20/L9-10).

Given Wittorff et al. teach that it was known to add chewing gum additives including pharmaceutically or biologically active substances to chewing gum base, it would have been obvious to one of ordinary skill in the art at the time of the invention to have done so in the gum base disclosed by modified Gmunder et al. Further, by doing so, the skilled artisan would produce a chewing gum that would provide the benefits of the pharmaceutical and biologically active substances.

Response to Arguments

11. Applicants' arguments with respect to claims 1-4 and 8-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, D. Lawrence Tarazano can be reached on (571) 272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH GWARTNEY/
Primary Examiner, Art Unit 1781